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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOON, SCARLETT Y	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,778	GROSS ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-63,68,69 and 75-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-63, 68, 69 and 75-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 March 2010 has been entered.

DETAILED ACTION

This Office Action is in response to Applicants' Amendment and Remarks filed on 9 March 2010 in which claims 1-57, 64-67 and 70-74 were previously cancelled, and claims 58 and 75 are amended to change the scope and breadth of the claims.

Claims 58-63, 68, 69 and 75-79 are pending in the instant application and are examined on its merits herein.

Priority

This application claims priority to U.S. provisional application no. 60/456,208 filed on 20 March 2003.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir 1994). Also see MPEP § 201.11.

The disclosure of the prior-filed applications, Application No. 60/456,208, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior filed application does not disclose the use of DMSO as an excipient.

Thus, the priority date of the instant claims **75-79** is deemed to be the filing date of the instant non-provisional application which provides support for the instantly filed claims, 19 March 2004. If Applicant disagrees, Applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

In clarifying the priority date of the instant claims, applicant should note or address whether the art rejections are prior to the priority date of the instant claims and whether said art occurred more than one year prior to said priority date.

Rejections Withdrawn

Applicants' amendment, filed 9 March 2010, with respect to the rejection of claims 58-63, 68, 69 and 75-79 under 35 USC § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, has been fully considered and is persuasive because the amended claim specifically indicates that "a dispensable sophorolipid compound" is obtained upon "formulating...with an excipient". This rejection is **withdrawn**.

Applicants' amendment and arguments, filed 9 March 2010, with respect to the rejection of claims 75-79 under 35 USC § 102(b), as being anticipated by journal publication by Bisht *et al.*, have been fully considered and are persuasive because Bisht *et al.* do not teach a method that encompasses formulating the resultant sophorolipids with DMSO at a concentration of 0.3 mg/mL, as instantly claimed. This rejection is **withdrawn**.

The following are new grounds or modified rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-63, 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by journal publication by Bisht *et al.* (of record).

Bisht *et al.* disclose chemo-enzymatic synthesis of well-defined sophorolipid analogues. Sophorolipids were synthesized by fermentation of the cells of Candida bombicola (formerly known as *Torulopsis bombicola* as evidenced by Carr *et al.*, PTO-892, Ref. W) on glucose/oleic acid mixtures, to give lactones and open chain forms of sophorolipids (p. 780, column 2, Figure 1; p. 781, column 2, subheading "Experimental Section," paragraph 1; p. 784, column 1, first paragraph). The synthesis of methyl and ethyl sophorolipid esters was conducted by reaction of the natural mixture with sodium methoxide or sodium ethoxide under reflux conditions (p. 784, column 2, Scheme 1; p. 784, column 2, subheading "Synthesis of Ester Sophorolipid Derivatives"). A detailed experimental procedure is provided for the methyl ester (compound 1),ethyl ester (compound 2), and butyl ester (compound 3) of the sophorolipids (p. 782, column 1, paragraphs 4 and 5; p. 782, column 2, first paragraph). The methyl, ethyl and butyl esters of sophorolipids were then subjected to lipase-catalyzed esterification with vinyl acetate or vinyl acrylate (p. 785, Scheme 2; p. 785-786, bridging paragraph) to yield regioselectively acylated sophorolipids. A detailed experimental procedure is provided for the synthesis of the 6',6"-diacetate derivative of the ethyl ester of sophorolipid (compound 6, p. 783, column 1, first full paragraph) butyl ester of sophorolipid (compound 7, p. 783, column 1, second full paragraph). Bisht *et al.* further disclose that sphorolipids have importance in the treatment of autoimmune disorders, regulation of angiogenesis, *in vivo* and *in vitro* antiendotoxic shock activity, and *in vivo* cancer

treatment/antitumor cell activity by cytokine upregulation (p. 781, column 1, first incomplete paragraph).

In the purification of compound 9, the sophorolipid analogue was eluted using a chloroform/methanol solvent mixture. It is the Office's position that chloroform/methanol are excipients. Thus, the purified product in a chloroform/methanol solution is considered to suffice as a dispensable solution of sophorolipids. Moreover, Applicants are requested to note that the recitation "to obtain the dispensable sophorolipid compound" is considered to merely state the results of the limitations in the claim. Thus, it adds nothing to the patentability or substance of the claim. When, as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

Applicants are requested to note that the recitation "having spermicidal and/or antiviral properties" is considered an inherent property of the sophorolipids. Products of identical chemical composition cannot have mutually exclusive properties. A chemical compound or composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or

claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See also MPEP § 2112.01. It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

Thus, the method for the preparation of sophorolipid analogues, disclosed by Bisht *et al.*, anticipates claims 58-63, 68 and 69.

Response to Arguments

Applicants' arguments, filed 9 March 2010, with respect to the rejection of claims 58-63, 68 and 69 made under 35 USC § 102(b) as being unpatentable over Bisht *et al.*, have been fully considered but they are not persuasive.

Applicants merely indicate that they continue to traverse this rejection and further submit that the amendment to claim 75 obviates the rejection as to claims 75-79. While the amendments to claim 75 obviate the rejection applied to claims 75-79, they do not overcome the rejection, modified above, applied to claims 58-63, 68 and 69.

Previously, Applicants argued that Bisht *et al.* do not disclose a method for formulating sophorolipids having spermicidal or virucidal properties. Moreover, Applicants argue that Bisht *et al.* do not suggest that the sophorolipid esters can be formulated with an excipient for dispensing the sophorolipid compound. These arguments are not persuasive for reasons of record. Specifically, it is reiterated that any solution comprising sophorolipids is considered to be dispensable, and thereby meets the limitations of the instant claims of formulating the resultant sophorolipid with an excipient. Furthermore, the method steps taught by Bisht *et al.* are the same as that

claimed in steps (a) through (d) of claim 58, wherein purification of a mixture resulting in a composition comprising the sophorolipid compound in a chloroform/methanol mixture, as taught by Bisht *et al.*, is equivalent to formulation of the sophorolipid compound with an excipient of the instant claims. As the instant claims do not recite any particular excipient and also do not require that the excipient be a pharmaceutically acceptable excipient, the use of chloroform/methanol in the prior art is deemed to meet the instant claim limitations for an excipient. Thus, the steps disclosed by Bisht *et al.* would necessarily result in a dispensable sophorolipid compound, thereby anticipating the instant claims.

Thus, the rejection is still deemed proper and is therefore maintained, as modified above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Section [0001]

Claims 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over journal publication by Bisht *et al.* (of record), in view of U.S. Patent No. 5,981,497 to Maingault (PTO-892, Ref. A), in view of publication by Kandil *et al.*, (PTO-892, Ref. U), in view of chapter publication by Wilkinson *et al.* (PTO-892, Ref. V), in view of chapter publication by Chattaraj *et al.* (PTO-892, Ref. W).

The teachings of Bisht *et al.* are as disclosed above in the claim rejections under 35 USC § 102.

The teachings of Bisht *et al.* differ from that of the instantly claimed invention in that Bisht *et al.* do not expressly teach formulation of the sophorolipid compound in DMSO at a concentration of 0.3 mg/mL.

The Maingault '497 patent teaches that sophorolipids having the structures as shown in formula (1) and (2) are therapeutically active substances useful in the treatment of the skin. The sophorolipids have a pro-inflammatory activity since they show a strong capability of activating monocytes and macrophages *in vitro* that is exemplified by the release of IL-1 (column 3, lines 54-58). The sophorolipid compound can be used as an activator of macrophages, as a fibrinolytic agent, as a healing agent in particular the treatment of wounds, or as an agent that promotes desquamation because of its effect on the cohesion of the corneocytes, or as a depigmenting agent, or else as a partial inhibitor of melanogenesis in particular for the treatment of brown spots (column 2, lines 33-40). Pharmaceutical compositions usually have a concentration of 0.01 to 5% by weight of sophorolipidic compound, but the conceivable range can be between 0.01 and 35% (column 5, lines 52-56). Applicants limitation of 0.3 mg/mL is equivalent to a concentration of 0.03%, and thus, the disclosure of the prior art meets the concentration limitations of the claim. Examples 1-3 illustrate various formulations of the sophorolipid compound. The disclosed uses of sophorolipids are implemented only in connection with topical application, although it is also found that pharmaceutical and cosmetic preparations can have very similar, if not identical forms (column 8, lines 38-43). Example 3 further discusses the use of the sophorolipid compounds as partial inhibitors of melanogenesis and in particular as depigmenting agents or for the treatment of brown spots in therapeutics or in cosmetics (column 7, lines 51-66).

Kandil *et al.* disclose a method for the treatment of sepsis comprising intravenous administration of sophorolipids (5 mg/kg) to rats (S40, column 2, bottom abstract). The

results showed that sophorolipids treatment significantly improved survival of rats with septic shock.

Wilkinson *et al.* teach the different methods by which a practitioner commonly administers drugs. Drugs are commonly administered orally or parenterally. Drugs can also be applied topically to the mucous membranes (p. 8, column 1, subheading "Topical Application"). Occasionally, systemic absorption is the goal of topical application. Few drugs readily penetrate the intact skin. Absorption through the skin can be enhanced by suspending the drug in an oily vehicle and rubbing the resulting preparation into the skin (p. 8, column 1, subheading "Skin").

Chattaraj *et al.* teach the incorporation of suitable vehicles or other chemical compounds into transdermal delivery systems. Substances that help promote drug diffusion through the stratum corneum and epidermis are referred to as skin-penetration enhancers, accelerants, adjuvants, or sorption promoters (p. 5). Ideal penetration enhancers should have the following characteristics: 1) Be both pharmacologically and chemically inert and chemically stable; 2) A high degree of potency with specific activity and reversible effects on skin properties; 3) Show compatibility with formulation and system components; 4) Be nonirritant, nonsensitizing, nonphototoxic, and noncomedogenic; 5) Be odorless, tasteless, colorless, and cosmetically acceptable; and 6) have a solubility parameter approximating that of skin (p.6, first paragraph). Table 1 provides an overview of some of the different chemical classes of chemical penetration enhancers, as well as examples of materials within the specific classes (p. 7-8). Dimethylsulfoxide is probably the earliest used and most extensively studied penetration

enhancer. It has broad spectrum activity, including the enhancement of penetration through both plant and animal membranes, and is known to enhance the permeation of various chemical agents by acting directly on the barrier (p. 6, last paragraph). Solutions of DMSO in concentrations exceeding 60% are particularly useful for increasing skin penetration of a wide range of ionic and nonionic compounds of molecular weights under 3000.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bisht *et al.*, concerning chemo-enzymatic synthesis of well-defined sophorolipid analogues and their potential application in a wide variety of fields, with the teachings of the Maingault '497 patent, regarding the therapeutic use of sophorolipids in treatments of the skin, with the teachings of Kandil *et al.*, regarding the treatment of sepsis comprising intravenous administration of sophorolipids, with the teachings of Wilkinson *et al.*, regarding the different routes of drug administration, with the teachings of Chattaraj *et al.*, regarding the use of chemical penetration enhancers to overcome the barrier properties of the skin for delivery of drugs and biomolecules.

Since Bisht *et al.* teach that sophorolipids have a potential application in a wide variety of fields and the Maingault '497 patent teaches that sophorolipids, at a concentration of 0.01% to 35%, are used in the treatments of skin, it would have been *prima facie* obvious for one of ordinary skill in the art to prepare the sophorlipid compounds disclosed by Bisht *et al.* at a concentration of 0.01% to 35% for topical application to the skin. Since the sophorolipid compounds disclosed by Bisht *et al.* are

structurally similar to the sophorolipid compounds disclosed in the Maingault '497 patent, one of ordinary skill in the art would reasonably expect the substitution to yield a predictable result, specifically, a composition useful for the treatments of skin.

Additionally, as Kandil *et al.* teach that another application of sophorolipids is in the treatment of sepsis, it would have been *prima facie* obvious for one of ordinary skill in the art to formulate the sophorolipid compounds for suitable administration for sepsis treatment. Although Kandil *et al.* administered the sophorolipids intravenously, Wilkinson teaches that the preparation of drugs for different routes of administration are routine and that while parenteral administration is common for systemic absorption, topical application intended for systemic absorption is also used. Wilkinson further teaches that when systemic absorption is the goal for topically administered drugs, a vehicle capable of transporting the drug through the skin is necessary. Thus, one of ordinary skill in the art would have been motivated to further combine the teachings of the prior art with Chattaaraj *et al.*, in order to receive the expected benefit, as suggested by Chattaraj *et al.* that chemical penetration enhancers are useful in overcoming the barrier properties of skin for the delivery of drugs and biomolecules. As chemical penetration enhancers are well-known in the art, the selection of the appropriate chemical penetration enhancer, such as DMSO, is considered routine to one of ordinary skill in art. Moreover, as the Maingault '497 patent teaches that their sophorolipid compositions are similar to those used in pharmaceutical and cosmetic preparations, one of ordinary skill in the art would reasonably expect that that their disclosed

concentrations are also useful in the treatment of sepsis when formulated appropriately and applied topically.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Section [0002]

Claims 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over journal publication by Bisht *et al.* (of record), in view of U.S. Patent No. 5,981,497 to Maingault (PTO-892, Ref. A), in view of chapter publication by Chattaraj *et al.* (PTO-892, Ref. W), in view of PG Pub No. US 2002/0141953 A1 to Ptchelintsev *et al.* (PTO-892, Ref. B).

The teachings of Bisht *et al.* are as disclosed above in the claim rejections under 35 USC § 102.

The teachings of Bisht *et al.* differ from that of the instantly claimed invention in that Bisht *et al.* do not expressly teach formulation of the sophorolipid compound in DMSO at a concentration of 0.3 mg/mL.

The teachings of the Maingault '497 patent are as disclosed above in section [0001] of the claim rejections under 35 USC § 103.

The teachings of Chattaraj *et al.* are as disclosed above in section [0001] of the claim rejections under 35 USC § 103.

Ptchelintsev *et al.* teach topical compositions for treating hyperpigmentation in human skin. The composition comprises a compound of formula (I) (paragraph 0012).

The composition may also further include, *inter alia*, skin penetration enhancers (paragraph 0027).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bisht *et al.*, concerning chemo-enzymatic synthesis of well-defined sophorolipid analogues and their potential application in a wide variety of fields, with the teachings of the Maingault '497 patent, regarding the therapeutic use of sophorolipids as depigmenting gents or for the treatment of brown spots of the skin in therapeutics or in cosmetics, with the teachings of Chattaraj *et al.*, regarding the use of chemical penetration enhancers to overcome the barrier properties of the skin for delivery of drugs and biomolecules, with the teachings of Ptchelintsev *et al.*, regarding topical compositions for the treatment of hyperpigmentation.

Since Bisht *et al.* teach that sophorolipids have a potential application in a wide variety of fields and the Maingault '497 patent teaches that sophorolipids, at a concentration of 0.01% to 35%, are used in the treatments of skin, it would have been *prima facie* obvious for one of ordinary skill in the art to prepare the sophorlipid compounds disclosed by Bisht *et al.* at a concentration of 0.01% to 35% for topical application to the skin. Since the sophorolipid compounds disclosed by Bisht *et al.* are structurally similar to the sophorolipid compounds disclosed in the Maingault '497 patent, one of ordinary skill in the art would reasonably expect the substitution to yield a predictable result, specifically, a composition useful for the treatments of skin. Moreover, as the Maingault '497 patent teaches that the sophorolipid compounds are useful as topical agents for the treatment of brown spots of the skin, and Ptchelintsev *et*

al. teach that skin penetration enhancers are useful in topical compositions for the treatment of hyperpigmentation, it would have been *prima facie* obvious for one of ordinary skill in the art to substitute the water carrier used in the formulations disclosed in the Maingault '497 patent with a chemical penetration enhancer, such as DMSO, or alternatively, further include DMSO into the topical formulation, as Chattaraj *et al.* teach that DMSO is known to enhance the permeation of various agents by acting directly on the skin barrier. One of ordinary skill in the art would have been motivation to combine the teachings and include a skin penetration enhancer, such as DMSO, into the topical formulation for the treatment of brown spots, in order to receive the expected benefit, as suggested by Chattaraj *et al.* that chemical penetration enhancers are useful in overcoming the barrier properties of skin for the delivery of drugs and biomolecules. As chemical penetration enhancers are well-known in the art, the selection of the appropriate chemical penetration enhancer, such as DMSO, is considered routine to one of ordinary skill in art.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicants' arguments, filed 9 March 2010, with respect to the rejection of claims 58-63, 68 and 69 made under 35 USC § 102(b) as being unpatentable over Bisht *et al.*, have been fully considered and are persuasive. Therefore, the rejection has been

withdrawn. However, upon further consideration, a new ground(s) of rejection is made, as applied in the rejection above.

Applicants argue that the amendment to claim 75 obviates the rejection as to claims 75-79. The amendment to claim 75 includes limitations wherein the excipient is DMSO and that the concentration is 0.3 mg/mL. The Maingault '497 patent teaches pharmaceutical compositions having a concentration of between 0.01 to 35% by weight of sophorolipidic compound. Chattaraj *et al.* disclose the use of skin penetration enhancers, such as DMSO, in topical formulations. Thus, the instantly claimed invention is *prima facie* obvious over the combined teachings of the prior art, as discussed in the rejections above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623